IN THE UNITED STATED DISTRICT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE:	)	CLASS ACTION
BUDEPRION XL MARKETING AND	)	
SALES PRACTICES LITIGATION	)	2:09-CV-2811 (Lead Case)
(MDL 2107)	)	
	)	
	)	

ADMINISTRATIVE CLASS ACTION COMPLAINT

Plaintiffs Micki Sackler and Andrew Richards ("Plaintiffs") submit this Administrative Class Action Complaint against Defendants TEVA PHARMACEUTICALS USA, INC. ("Teva") and IMPAX LABORATORIES, INC. ("Impax") (sometimes collectively referred to herein as "Defendants") for MDL 2107. A full and complete list of all cases that are currently a part of this MDL is attached hereto as Exhibit A. In addition to serving as the administrative complaint for non-personal injury claims in MDL 2107, this Administrative Class Action Complaint also amends and supersedes the original California state pleading to add new class representatives and expand the relief sought for a nationwide class versus a California-only class. For their Complaint against Defendants, Plaintiffs allege as follows:

NATURE OF THE ACTION

1. This is a national FRCP 23(b)(2) class action for injunctive and other equitable and statutory relief, including restitution, against Defendants for their unlawful business practices, fraudulent omissions and failure to warn about the differences between Wellbutrin XL ("Brand Product") and Defendants' generic substitute, "Budeprion XL (300mg)" and Impax's "Bupropion Hydrochloride XL (150mg) (collectively referred to herein as "Impax Product"). Because of such differences—which were known to Defendants at all relevant times—including

but not limited to the different drug release mechanisms, Defendants were obligated to disclose (or otherwise warn) doctors, pharmacies, and consumers about various matters itemized below. These include, but are not limited to, the need for doctors to closely monitor patients who are being transitioned or graduated from the Brand Product, or other generic formulation, to the Impax Product.

FACTUAL ALLEGATIONS

The Generic Drug Industry

2. The generic drug industry is big business. In 2007 alone, generic drug manufacturers netted more than $58 billion in sales in the United States. The demand for generic drugs is driven by consumers as well as pharmacies, which generally enjoy substantially higher profit margins when they substitute a generic medication for the branded.

3. Generic drugs (including the Impax Product) are generally much cheaper than their branded counterparts.

4. Drug development for branded products is extremely time consuming and costly. On average, brand-name drug companies spend about $800 million to discover, develop, and produce a new drug. They then have to charge fairly high prices to recoup their investment and actually make a profit.

5. Brand products must be approved by the U.S. Food and Drug Administration ("FDA"). The approval process, a New Drug Application ("NDA"), can be quite intensive, requiring numerous studies regarding the drug's efficacy and safety.

6. Generic drugs are approved differently, in what is called the "Abbreviated New Drug Application" process ("ANDA"). A generic drug sponsor need only show that the drug includes the same active ingredients, dosage form, strength, route of administration as, and is

bioequivalent to, the drug that it is mimicking.

7. To show bioequivalence, the FDA requires an applicant to submit evidence comparing the proposed drug to the branded drug (often called the reference drug in the applications). The standard method for proving bioequivalence is a two-treatment crossover study on a group usually consisting of between 24 and 36 "healthy" (for example, non-depressed individuals for an anti-depressant) volunteers. Single doses of the test drugs are administered to the subjects and blood and plasma levels of the test subjects are measured over time.

8. To be bioequivalent, the proposed drug must have a confidence interval within 80% and 125% of the reference drug with regard to Cmax and AUC. Cmax refers to the maximum plasma concentration for a drug. AUC ("area under the curve") is the area under the curve created by plotting the concentration of a drug in blood plasma over time.

9. Though not required for the FDA's definition of bioequivalence, Tmax is another important measure. Tmax refers to the point in time after dosing when Cmax occurs.

10. Plaintiffs at no time in this lawsuit challenge any "bioequivalency" determination by the FDA. Rather, this suit focuses on Defendants' post-approval conduct and failure to disclose critical information when it became readily apparent that something was wrong with their product. Defendants' motive for their fraudulent omissions is clear: to protect and prolong the enormous profit stream created by the Impax Product.

Bupropion Hydrochloride: an Atypical Antidepressant

11. Bupropion Hydrochloride ("Bupropion") is the active ingredient in the Brand and generic products (including the Impax Product).

12. Bupropion was, and is, prescribed for conditions including depression, major depressive disorder, seasonal affective disorder, Selective Serotonin Reuptake Inhibitor

("SSRI")-induced sexual dysfunction, and smoking-cessation.

13. By 2007, Bupropion Hydrochloride was the fourth-most prescribed antidepressant in the United States, with over 20 million retail prescriptions written annually.

14. Bupropion is a relatively weak inhibitor of the neuronal uptake of norepinephrine, serotonin, and dopamine.

15. It is chemically unrelated to the more popular SSRI anti-depressive agents.

16. The mechanism of action[1] of Bupropion is unknown.

17. However, Bupropion's effect on norepinephrine and dopamine is generally believed to cause its anti-depressive effect.

18. Bupropion is extensively metabolized by the human system. The parent drug, when ingested, interacts with Cytochrome P450 ("CYP") enzymes in the human body, which biotransforms Bupropion into three key metabolites: hydroxybupropion, erthyrobupropion, and threohydrobupropion ("the metabolites").

19. The metabolites are pharmacologically active, and are present in blood plasma concentration at levels as high or higher than the dose of Bupropion. These metabolites are thought to affect both efficacy and adverse effects, though the potency and toxicity of the metabolites relative to Bupropion have not been fully characterized. This sets Bupropion apart from other types of antidepressants (such as SSRIs), wherein the metabolites play a less significant role in the drug's therapeutic impact and side effects.

20. Taking Bupropion can result in certain adverse side effects, including headaches, migraines, agitation, tremor, nervousness, dizziness, irritability, decreased memory, sweating, insomnia / sleep disturbances, abdominal pain, nausea, constipation, diarrhea, vomiting, dry

[1] In pharmacology, the term mechanism of action (MOA) refers to the specific biochemical interaction through which a drug substance produces its pharmacological effect. A mechanism of action usually includes mention of the specific molecular targets to which the drug binds, such as an enzyme or receptor.

mouth, chest pain, palpitations, and/or flushing. Because Bupropion lowers the seizure threshold, one of the major risks associated with Bupropion is seizures. Improper dosing exacerbates and increases these risks.

The Evolution of Wellbutrin

21. Bupropion was first introduced into the market by GlaxoSmithKline Corporation ("GSK") in the late 1980s, marketed under the trade name "Wellbutrin."

22. At first, GSK only offered Wellbutrin in an immediate-release form ("Wellbutrin IR"), which required the patient to take three pills every day. Wellbutrin IR utilized a simple matrix release mechanism, wherein the pill dissolved rather quickly and metabolized in the upper gastrointestinal ("GI") tract. Wellbutrin IR has a Tmax of two hours.

23. In other words, Wellbutrin IR users prescribed 300mg daily took 3 pills each day, each 100mg, wherein the blood concentration of Bupropion from each 100mg pill peaked after two hours.

24. Days before Wellbutrin IR was to hit the market, a study was released showing that 10% of users who also suffered from anorexia–bulimia have seizures when on the drug. Understandably, this delayed the launch of Wellbutrin IR and underscores the serious effects that can result from an excess of Bupropion.

25. In 1996, GSK introduced into the market a twice-a-day sustained-release formulation of Bupropion ("Wellbutrin SR"). Rather than file a full New Drug Application, GSK was permitted by the FDA to rely upon the data submitted in the Wellbutrin IR NDA and obtain approval of the SR dosage form by demonstrating bioequivalence to the IR product. Wellbutrin SR also employed a matrix release mechanism. It has a Tmax of three hours, and is also metabolized in the upper GI tract.

26. Thus, Wellbutrin SR users prescribed 300mg daily took 2 pills each day, each 150mg, wherein the blood concentration of Bupropion from each 150mg pill peaked after three hours.

27. Because the matrix technology released Bupropion in the upper GI tract, the rate and total amount of Bupropion fluctuated depending on a number of factors, including food consumption, alcohol consumption, concomitant medications, and other GI issues.

28. This matrix technology was prone to dose dumping, meaning there was a quicker rate of absorption when the pill was taken with food. Though GSK did not at the time of its drug application feel the amount of dose dumping was clinically significant, it disclosed this information to consumers and physicians so they could make informed decisions regarding treatment. The Wellbutrin SR label read:

> **Absorption**: Following oral administration of WELLBUTRIN SR Tablets to healthy volunteers, peak plasma concentrations of bupropion are achieved within 3 hours. Food increased Cmax and AUC of bupropion by 11% and 17%, respectively, indicating that there is no clinically significant food effect.

29. The generic manufactures or Wellbutrin SR, including Impax, also made this disclosure on the labels of their generic formulations of the SR product.

30. Though Wellbutrin SR was an improvement on the IR version, patient compliance with a Bupropion regimen is best served by a once-a-day formulation. In 2003, GSK introduced a once-a-day extended release formulation called "Wellbutrin XL."

31. Unlike its predecessors, Wellbutrin XL employed a sophisticated membrane-release technology, whereby the drug was not released through a dissolving pill, but seeped at a controlled rate through a membrane that actually passed through the entire GI tract intact.

32. The Tmax for Wellbutrin XL was five hours, which is the estimated time for a pill

to move into the lower GI tract after ingestion. With release occurring in the lower GI tract, the total amount of Bupropion released was only nominally impacted by food, alcohol, concomitant medications, and other variables. As this release mechanism solved the dose dumping problem, GSK updated its label to say that "food did not affect the Cmax [the total amount of drug in the bloodstream]…of bupropion."

33. The GSK release mechanism thus allowed a patient to receive a steady amount of the drug over a 24 hour period, crucial for any once-a-day pill.

34. GSK contracted with Biovail Corporation and spent considerable time and resources perfecting its membrane release technology and protected it under patent. Generic manufacturers, therefore, had to develop an XL product with a release profile similar to that of Wellbutrin XL without infringing upon Biovail's patent.

35. Most generic manufacturers were able to do so, utilizing a similar membrane technology. Watson Pharmaceuticals and Anchen Pharmaceuticals, for example, developed a generic bupropion XL product with a membrane release technology.

36. Impax however, the generic manufacturer that was able to quickly capture the lion's share of the market, did not evolve with its colleagues.

The Impax Product: an Immediate Release "Extended Release" Product

37. Impax submitted the ANDA for Bupropion Hydrochloride XL (150mg), on November 30, 2004.

38. Shortly thereafter, Impax submitted an amendment to that ANDA for a new product strength—the Budeprion XL (300mg) product.

39. Anchen Pharmaceuticals was the first Wellbutrin XL generic to be approved by the FDA, and received the coveted 180-day exclusivity rights given to the first generic approved.

Anchen in turn waived its exclusivity rights to Teva who then marketed the Impax Product during the 180-day exclusivity period. Teva/Impax paid Anchen for these exclusivity rights..

40. Teva/Anchen/Impax then successfully defended a patent infringement suit brought by Biovail relating to the release mechanism, a standard industry move which delays the launch of the generic product.

41. The Impax Product (generic versions of Wellbutrin XL that are the subject matter of this litigation) entered the market in late 2006/early 2007. The Impax Product did not, as did Wellbutrin XL or other generics, employ a membrane release mechanism. Rather, the Impax product continued to rely on matrix technology, and attempted to rely on the sheer size of the pill in an attempt to control release. *See* Exhibit B (color photographs of the Impax Product, Wellbutrin XL, and the Watson generic).

42. The Impax product also contained more excipient ingredients than the more sophisticated Brand Product (or Watson/Anchen generic product).

43. The Tmax for the Impax Product was 2 hours – the 300mg pill, the highest dose of Bupropion on the market, peaked in just two hours, versus five hours in an individual on the Brand Product or other generics (such as Anchen or Watson).

44. The Impax Product's release mechanism caused it to break apart quicker than the Brand Product and metabolize in the upper gastrointestinal tract. This made the amount and rate of Bupropion released dependent on a number of factors, such as food consumption, alcohol consumption, other medications, and other GI issues. Users of Wellbutrin XL, in contrast, achieved peak performance without monitoring the conditions surrounding their ingestion of the pill.

45. Defendants know that physicians and consumers prefer the once-a-day

formulation, even though it is more expensive, because the ease of use of the XL product assists with patient compliance and enables physicians to better treat their patients.

46. The Impax Product is less effective, more risky, and fails to even provide the ease-of-use of the Brand Name once-a-day product (since users must monitor the conditions under which they ingest the pill).

47. The Average Wholesale Price ("AWP") for a 30 day supply of a generic SR Bupropion product is roughly $115 while the AWP of a generic XL Bupropion product is roughly $150.

48. Despite the differences between the Brand and Impax Products, the Impax Product meets the regulatory definition of "bioequivalent," a determination Plaintiffs do not challenge. As noted below, post-approval information made Defendants aware that these differences were material. This knowledge imposed upon them a duty to disclose, which it could have easily done, but chose not to in order to protect their market share, despite the apparent harm to consumers.

49. Plaintiffs are informed and believe that Defendants, starting in late 2006, have manufactured, distributed, licensed, and/or sold a generic version of Wellbutrin XL (300mg formulation) with the trade name "Budeprion XL" throughout the United States including California.

50. Impax further manufacturers a 150mg formulation simply called "bupropion hydrochloride XL" which is distributed by its wholly owned subsidiary, Global Pharmaceuticals.

51. Compared to Wellbutrin XL and other generics, the Impax Product contains an inferior delivery mechanism.

52. The more rapid release of Bupropion from the Impax Product makes it less

effective in treating depression and more likely to cause certain dangerous side effects than the Brand Product or other generic formulations.

53. As indicated below, Defendants have withheld material information about the Impax Product from doctors, pharmacies, patients, and insurers (including Plaintiffs and their physicians).

Post-Approval Complaints Mount & Consumer Groups Take Action

54. Following the emergence of the Impax Product on the market, complaints—from consumers, consumer watchdog groups, and other sources—came pouring in, not only to the FDA but to numerous consumer groups.

55. Patients who had successfully been treated with Wellbutrin XL for years were experiencing adverse side effects for the first time after being switched the Impax Product.

56. Additionally, many patients reported that the Impax Product was not effectively treating their depressive symptoms.

57. Patients who later switched back to Wellbutrin XL or an alternate generic (such as that manufactured by Watson Pharmaceuticals) experienced immediate relief of their depressive symptoms and a lessening or elimination of side effects.

58. Thus loss of efficacy associated with the Impax Product was not due to lapse of drug effectiveness that occurs with some long-term users.

59. As post-approval reports of problems came pouring in, Defendants became aware of the materiality between the different release profiles (Cmax, Tmax, and dose dumping) of the Impax and Brand Products, and knew that patients should be carefully monitored, yet failed to disclose these facts or otherwise warn of these material differences.

60. Defendants continued to maintain that the release profile of the Impax Product

was identical to the Brand Product, though it knew this to be false and material.

61. Defendants failed to disclose this information in order to protect their market share. (These omissions and misrepresentations are described in greater detail below).

62. Defendants' motive in hiding the truth is obvious. Even with the limited information that has become available as a result of FOIA requests, independent studies, and this lawsuit, Defendants' sales have fallen significantly. As was recently reported, "[a] generic version of Wellbutrin XL, marketed by Teva Pharmaceutical Industries Ltd. (TEVA) as Budeprion XL, has been the subject of patient complaints about side effects and lack of efficacy. The drug, which used to be the market leader, has fallen to third place behind copycats made by Actavis Group (ACT-IC) and Watson Pharmaceuticals Inc. (WPI)."[2]

63. Meanwhile, while it represented to the general public that the product's release profile was the same as the Brand Product, Impax defended patent litigation initiated by Biovail over Impax's release mechanism. In that case – in which all evidentiary data was filed under seal away from the public's view – Impax lauded the numerous differences between the release mechanisms in its successful defense. *See e.g., Biovail Laboratories, Inc. v. Impax Laboratories, Inc.*, No. 05-1085 (E.D. PA, filed March 7, 2005). (This patent litigation is not surprising given that brand name manufacturers often initiate patent litigation or a "Citizens Petition" with the FDA to delay the release of generics on the market, protecting their monopoly. The relief in these actions rarely addresses concerns of consumer safety; rather they have one goal: to eliminate competition.).

64. Since Defendants refused to release the data in their possession to consumers and their physicians, consumer groups were forced to undertake their own studies. In late 2007, Consumerlab, an industry watchdog group, conducted test-tube ("*in vitro*") dissolution studies,

[2] Andy Georgiades, *Biovail's Wellbutrin XL Keeps Status with Some Insurers*, WALL. ST. J. (Feb. 22, 2010).

and found that Budeprion XL (300mg) released 34 percent of its Bupropion in the first hour, compared to only 8 percent in 300mg of Wellbutrin XL. Still Defendants did not disclose this information and continued to represent that its release profile was identical to that of the Brand Product.

65. As noted by Consumerlab, "[a]fter switching to the generic formulation, Budeprion XL 300mg, many reported symptoms such as headaches, irritability, nausea and insomnia—known side effects of bupropion. Other shared stories of becoming easily upset or aggressive, crying, gaining weight or experiencing a return of depressive symptoms. Some reported thoughts of suicide while taking the generic form of Wellbutrin."[3]

66. Two months later, the United States Pharmacopeia ("USP"), the official Public standards-setting authority for all prescription medications, released information indicating that Budeprion XL (300mg) released between 25 and 50 percent of its Bupropion in two hours, compared to less than 20 percent for Wellbutrin XL (300mg). Defendants to this day continue to represent on their label that USP results are "still pending", withholding vital information about the test results.

67. Around this time numerous media reports surfaced describing the tragic circumstances surrounding individuals experience with Budeprion XL 300mg, which is manufactured and distributed by Defendants.[4]

68. With the public and medical community demanding information regarding

[3] Consumerlab.com, *Drug Tests:; Wellbutrin vs. Generic Bopropion*, last modified Jan. 30, 2008, at http://www.consumaerlab.com/review/Wellbutrin_vs_Generic_Bupropion/Wellbutrin/.

[4] *See, e.g.*, Jacqueline Stenson, *Report Questions Generic Antidepressant*, MSNBC (Oct. 12, 2007) at http://www.msnbc.msn.com/id/21142869/; Joanne Silberner, *Generic Not Same as Brand Antidepressant?*, Nat'l Public Radio (Oct. 12, 2007) at http://www.npr.org/templates/story/story.php?storyId=15218354; The People's Pharmacy, *Generic Drug Equality Questioned* (Oct. 12, 2007) at http://www.peoplespharmacy.com/2007/10/12/generic-drug-eq/; *see also* Lesley Alderman, *Not All Drugs Are the Same After All*, N.Y. TIMES (Dec. 18, 2009) at http://www.nytimes.com/2009/12/19/health/19patient.html; Katerine Eban, *Bad Bargain*, Self Magazine (June 2009) at http://www.self.com/health/2009/06/dangers-of-generic-drugs.

generic XL Bupropion, Defendants still did not disclose the pharmacokinetic differences between their drug and the Brand Product, and continued to mislead the medical community and consumers that there were no release profile differences between the Impax Product and the Brand Product. Defendants also continued to mislead as to the testing done on the product (or lack thereof).

69. Finally, in April of 2008, under intense public pressure from consumers, non-profit watchdogs, and the medical community, the FDA hurriedly issued a report in which it explained some of the differences between the Impax Product and Wellbutrin XL and the lack of testing on the 300mg product. The FDA made no determination as to whether Defendants' warnings were adequate.

Defendants' Omissions and Misrepresentations

70. With widespread complaints about the Impax product, consumers and physicians searching for answers received no disclosures from Defendants---rather, Defendants continued to put forth misinformation in an attempt to deceive consumers and physicians and protect their competitive advantage.

71. Defendants' material omissions include:

(a) Defendants do not disclose that the time after ingestion to which the Impax Product's maximum level of Bupropion appears in the bloodstream (or Tmax) is just two hours. Rather, Defendants continue to represent on their label that "[f]ollowing oral administration of Budeprion XL to healthy volunteers, time to peak plasma concentration was approximately 5 hours[.]"

(b) Defendants do not disclose that the Tmax of hydroxybupropion (one of the key metabolites) shorter than that of the Impax Product. Rather, Defendants assert that "peak plasma concentrations of hydroxybupropion occur at approximately 7 hours after administration of Budeprion XL."

(c) Defendants do not disclose that, unlike the name brand product, taking the Impax Product with food (and possibly alcohol) increases the total amount of the drug eventually released into the body (Cmax) which can cause adverse events.

Rather, Defendants insisted that "food did not affect the Cmax or AUC of bupropion" and that "Budeprion XL may be taken without regard to meals." This is despite the fact that Defendants disclosed the dose dumping propensities of the SR product;

(d) Defendants do not disclose that the 300mg Impax Product was never even tested for bioequivalence with the Brand Product. Rather, Defendants stated that there had been conducted "a study comparing 14-day dosing with Budeprion XL tablets 300mg once daily to the IR formulation of bupropion" as well as "a study comparing the 14-day dosing with Budeprion XL tablets 300mg once daily to the SR formulation of bupropion[.]";

(e) Defendants do not disclose the existence of dissolution tests by United States Pharmacopeia ("USP") indicating dissolution of the Impax Product varied significantly from the Brand Product. Rather, Defendants continue to represent that the "USP drug release test is pending" -- nearly three years after the testing was completed;

(f) Defendants did not disclose the numerous complaints of adverse events and loss of efficacy by countless consumers who switched from Wellbutrin XL to the Impax Products;

(g) Defendants do not warn that a patient being switched from Wellbutrin XL to the Impax Product should be carefully monitored by his and her physician;

(h) Defendants do not disclose that consumers have to carefully monitor the circumstances under which they take the Impax Product, a disadvantage not associated with the Brand Product (which undermines a physician's compliance goal of once-a-day products);

(i) Defendants did not disclose that the dissolving pill Budperion XL begins to metabolize in the upper gastrointestinal tract, rather than in the lower gastrointestinal tract as does Wellbutrin XL;

(j) Defendants did not disclose that the Impax Product had a different physiological and therapeutic effect than Wellbutrin XL, despite Impax's claim on its website of "formulation expertise to develop products that reproduce the brand name product's physiological characteristics"[5];

(k) Defendants did not disclose that the Impax Product used an inferior and old matrix release technology, yet the Impax website boasts of its "formulation expertise and unique drug delivery technologies"[6];

(l) Defendants did not disclose they were aware that the Impax Product did not work

[5] http://www.impaxlabs.com/generic.php.
[6] http://www.impaxlabs.com/mission.php.

the same as Wellbutrin XL, yet Teva's website states that approved generic products such as the Impax Product "must work the same as the brand name product"[7]; and

(m) Defendants did not disclose that it is currently testing the efficacy of their 300mg product due to numerous consumer complaints and serious reported side effects.

72. Defendants knew that there were significant, material differences between the Impax Product and Wellbutrin XL, knew that patients should be carefully monitored, knew that patients needed to take extra steps than users of Wellbutrin XL to ensure efficacy, yet failed to warn of those material differences and need for monitoring.

73. Defendants knew about the different release profiles between the Impax and Brand Product, and as post-marketing complaints came pouring in, certainly became aware of the need to disclose these differences. But Defendants chose to ignore these issues for marketing purposes and to protect the market share of the Impax Product as against their competitors. Had Defendants disclosed the differences between the Impax Product and Wellbutrin XL, pharmacies would not have wanted to sell it and would have opted to sell one of the other Wellbutrin XL generics, such as the Watson generic (which utilizes a membrane release technology similar to Wellbutrin XL). Consumers likewise would have avoided the Impax Product.

74. Though meeting the regulatory criteria for bioequivalence, Defendants know that the Impax Product is less effective at treating depression and more prone to cause adverse events. There has been no testing nor is there any proof of efficacy of Defendants' product. The first test of the Impax Product on depressed individuals was its introduction onto the market, a test it failed considerably.

75. Defendants could have—and should have—disclosed the known differences between the Impax and Brand Product as soon as they learned of them or their significance, so

[7] http://www.tevausa.com/default.aspx?pageid=82.

that consumers and their doctors and pharmacies would be fully informed about the risks of the Impax Product. Defendants, however, chose not to make these disclosures.

76. If they had, the Impax Product would not have enjoyed its significant market share because doctors, pharmacies and consumers alike would have avoided it, especially given that there are other Wellbutrin XL generics on the market that employ the same membrane release technology as Wellbutrin XL and that have not had the same problems as the Impax Product.

77. Patients and their physicians were also not told that unlike the Brand and other generic products, the Impax Product required patient self-monitoring to achieve compliance (food intake, etc.). This burden, however, was not even disclosed by Impax to consumers, physicians, and pharmacists. Obscuring this burden gave Defendants a competitive advantage.

78. Defendants knew that often, pharmacies routinely and automatically substitute generic versions of prescription drugs when a doctor has prescribed the brand name product without informing consumers and/or their doctors of the substitution. Defendants also knew that patients sought an XL product for the ease of use of a once-a-day product, and any contrary disclosures would hurt their effort to corner that market. Defendants should have disclosed the known differences between Wellbutrin XL and the Impax Product, at the very least, so that doctors would have had the opportunity to monitor their patients and warn them about the risks and efficacy of the Impax Product.

79. The materiality of Defendants' omissions – i.e. that doctors, consumers, and pharmacies would avoid the Impax Product -- is evidenced by the fact that recently, following the disclosure of different release profiles by the FDA and media reports generated by the filing of this lawsuit, Defendants have seen a significant drop in market share. As was recently

reported, "[a] generic version of Wellbutrin XL, marketed by Teva Pharmaceutical Industries Ltd. (TEVA) as Budeprion XL, has been the subject of patient complaints about side effects and lack of efficacy. The drug, which used to be the market leader, has fallen to third place behind copycats made by Actavis Group (ACT-IC) and Watson Pharmaceuticals Inc. (WPI)."[8]

80. This action does not challenge the FDA's determination that the Impax Product is bioequivalent to Wellbutrin XL and may be sold. FDA standards which must co-exist with state law are loose enough that drugs with a radically different release mechanism can meet the FDA's minimal standards for generic approval as happened here. In some cases, including the instant case, those allowable differences are significant enough to warrant additional disclosures, which the FDA expressly allows but which Defendants have avoided.

81. Defendants are and have been aware since after submitting their application to the FDA that the Impax Product is less effective than Wellbutrin XL and other generic alternatives, and posed greater risks of adverse side effects.

Defendants' Deceit Wreaks Havoc on the Antidepressant Market

82. Consumers who had switched to the Impax Product and found their depression returning, or the onset of adverse events, had no way of knowing why this was happening. Nor did their physicians. Defendants hid the pharmacokinetic differences between the Impax Product and the Brand Product, asserting not only that it tested both the 150mg and 300mg product (not true as to the latter), but that the tests revealed an identical release profile to the Brand Product. Defendants also failed to disclose the results of the USP test results.

83. Defendants' omissions have led to mass confusion within the insurance industry, the medical community, and among the millions of Americans who are prescribed Bupropion.

84. Under current practice, doctors can legally write "DO NOT SUBSTITUTE" and

[8] Andy Georgiades, *Biovail's Wellbutrin XL Keeps Status with Some Insurers*, WALL. ST. J. (Feb. 22, 2010).

no generic product will be substituted for the brand name. Doctors cannot, however, direct a pharmacy not to fill a prescription with one version of a generic (i.e. "NO BUDEPRION" is not an option). Defendants have exploited this loophole.

85. Defendants' failure to disclose has stigmatized *all* generic formulations of Bupropion XL. Exasperated physicians who are unaware of the issues with the Impax Product are writing more "DO NOT SUBSTITUTE" prescriptions out of an abundance of caution even though viable generics exist (such as the Watson and Anchen products). Defendants' fraudulent unfair and deceptive business practices harm not only consumers, but other companies as well.

86. This effect is evident in that recently the Brand Product incredibly recaptured a portion of the overall Bupropion market, which is nearly unheard of with the introduction of generic medications. The Brand Product's market share is around 6.6%, above the 3%-4% that would be more typical given generic competition.[9]

87. Insurance companies are also unaware that the problem with generic Bupropion is limited to certain generics, and as a result have continued to give favorable reimbursement treatment to the Brand Product, costing insurers millions of dollars and raising premiums for all.

88. This was revealed in a February 22, 2010 Wall Street Journal article, which explained:

> Two top U.S. health insurers continue to give favorable reimbursement treatment to Biovail Corp.'s (BVF) Wellbutrin XL drug, which some patients believe works better than generic alternatives.
>
> Aetna Inc. (AET) and Cigna Corp. (CI) have kept the once-daily antidepressant on the middle tier of their formularies - the lists of drugs covered under managed-care companies' health plans. Formularies have three main tiers. Tier 1 medicines are usually low-cost generics with the lowest co-pays for patients; Tier 2 drugs are mostly preferred brand-name drugs with slightly higher co-

[9] *Id.*

> pays; and Tier 3 drugs are higher-cost branded drugs with the highest co-pays.
>
> It's common for insurers to move drugs like Wellbutrin XL to the third tier once a generic becomes available, which was the case with antidepressants like Prozac, Zoloft, and Celexa.
>
> "Aetna decided to keep Wellbutrin XL as a preferred brand-name second-tier drug because we found that it worked best for some patients," said company spokeswoman Kate Prout. "The generic alternative is available to members on the first tier. Aetna made this decision in 2008 and reviewed the decision again in 2009."[10]

89. Meanwhile, due to the mass confusion caused by Defendants' omissions, Biovail has announced they are actually *increasing* the cost of the Brand Product.[11] Defendants' deceptive business practices have turned the generic market on its head, resulting in higher prices for all.

90. Due to the unlawful, unfair and deceptive business practices instituted by Defendants as part of their nationwide marketing scheme to dominate the market among Wellbutrin XL generics, the Impax Product was rapidly substituted for the name brand product. According to the FDA, in 2007 600,000 prescriptions were written *every month* for the Impax Product, making it at that time the clear leader of market share among the generics and providing substantial revenue to Defendants – revenue that it would not had received had it properly made disclosures, as evidenced by its recent plunge in market share. In 2009, more than 1 million prescriptions were filled with the 150mg Impax Product and over 3 million with the 300mg Impax Product.

91. Defendants' unlawful, unfair and deceptive business practices have harmed consumers, have stigmatized good generics and harmed competitors, have led confused doctors to raise health care costs by writing "DO NOT SUBSTITUTE" despite the availability of

[10] *Id.*
[11] Andy Georgiades, *Biovail Seen Raising Wellbutrin XL Price in 2010*, WALL ST. J. (Feb. 23, 2010).

effective generics, and have led major health insurance companies to incur millions of dollars by keeping the Brand Product on their formularies. In short, Defendants' fraudulent business practices have wreaked havoc on the Bupropion industry.

The "New" Study: Defendants Stall for Time

92. In November 2009—after a flurry of complaints from customers and only five months *after* the first of these lawsuits against Defendants was filed—Impax announced they will for the first time conduct and fund a clinical study of Budeprion XL (300mg).

93. Though the public interest dictates that this study's protocol should be made public before testing begins, Defendants have refused to release it.

94. The study, which will take place in California, will compare two formulations of Wellbutrin (300mg) tablets and Defendants' Budeprion XL (300mg), and include patients diagnosed with depression who have reported adverse events or lack of effect when taking Budeprion XL (300mg).

95. Defendants decided to conduct this study voluntarily, and have indicated that they will disclose the results upon its completion.[12] The FDA did not order Defendants to do this study. It is conducted because the complaints and reports of adverse effects have resulted in a slip in market share, costing Defendants millions of dollars.

96. Defendants have indicated that they plan to keep consumers and their physicians in the dark regarding the differences between their product and Wellbutrin XL until this study is completed. Defendants have revealed in their position statement that this study "will take at least a year, and possibly much longer, to complete."

97. This is despite the fact that the study of its 150mg product used in its FDA submission took less than a month to complete.

[12] Andy Georgiades, *Teva, Impax Plan Generic Wellbutrin XL Study*, WALL ST. J. (Nov. 9, 2009)

98. Presumably, during this "year, and possibly much longer," Defendants will continue to reap huge profits from the sale of their generic. Upon information and belief, gross sales of the 300mg Impax Product topped $400 million in 2009 alone. Defendants will continue to defraud and mislead consumers and make hundreds of millions of dollars off of their deceptive scheme at the expense of disabled persons nationwide. The study, with its "secret protocol", may exist only to extend the life of this product, that sees its market share dwindling as its faults are exposed.

California's Interest in a California Corporation's Business Practices

99. This lawsuit seeks to apply California's statutory business standards to a California drug manufacturer (Impax) and its distribution partner (Teva) for uniform national conduct emanating from California.

100. Defendants engage in nationwide market activity, providing the same label with every Impax Product that omits material information. A national solution makes sense.

101. Plaintiffs seek to end Defendants' deceptive business practices of failing to disclose or warn about the differences between the Impax Product and Wellbutrin XL (as well as other generics).

102. The unfair, deceptive, and unlawful business practices for which Plaintiff seeks redress originated in California. The manufacturer, Impax, is headquartered there. Data submitted to the FDA was analyzed and summarized there. Decisions about design and warnings were made there. The product is manufactured there. The label (with its fraudulent omissions) was drafted there. A plurality of Impax Product consumers are California residents. The "year, and possibly much longer" test is taking place there. In short, the unlawful and deceptive business practices and acts alleged herein, which have affected members of the

proposed class throughout the United States, emanated from Impax's owners, managers, officers, directors, and/or employees in California, and were effectuated in California. Teva, with its headquarters in Pennsylvania, distributes only the 300mg version of the Impax Product.

103. California therefore has significant contacts with the Plaintiffs and the Class Members' claims. California also has a significant interest in preventing its businesses from breaking its laws regarding unfair business practices, as well as protecting its honest competitors and consumers.

104. California's sweeping Unfair Competition Law, California Business and Professions Code section 17200, *et seq.*, ("UCL") is a strict liability statute that proscribes unlawful, unfair or deceptive business practices. The UCL can be violated in three distinct and independent ways: practices that are unlawful, unfair or fraudulent. *In re Tobacco II*, 46 Cal. 4th 298, 311 (2009). The UCL focuses on the defendant's conduct and not the plaintiff's damages. *Id.* at 312, 324.

105. The California Consumer Legal Remedies Act, Cal. Civ. Code § 1750, *et seq.*, sets forth a list of 23 activities defined to be "unlawful". The remedies under the CLRA are supplemental to those available under other statutory and case law. Cal. Civ. Code § 1752. The CLRA has three elements: (1) the defendant's conduct was deceptive, (2) causation and (3) damages. Cal. Civ. Code § 1750. Here, Defendants' failure to warn among other things is deceptive.

106. The self-declared purposes of the act are 'to protect consumers against unfair and deceptive business practices and to provide efficient and economical procedures to secure such protection. Cal. Civ. Code § 1760.

107. While the only monetary relief available under the UCL is restitution and there is

no provision for attorney fees, the CLRA allows for restitution, damages, punitive damages, statutory damages and attorney fees. A plaintiff may also "obtain an order enjoining the methods, acts, or practices." Cal. Civ. Code § 1780(a)(2)-(a)(5).

108. In addition, the CLRA has enhanced penalties for acts perpetrated against disabled persons. If the defendant's conduct is directed at a class of persons who are "disabled", a $5,000.00 civil penalty may be awarded to "each class member". Cal. Civ. Code § 1780(b). A "disabled person" is someone who has a "physical or mental impairment which substantially limits one or more major life activities." Cal. Civ. Code § 1761(f),(g). Individuals suffering from major depressive disorder are "disabled."

109. Because the CLRA's 23 prohibited acts are all declared by statute to be "unlawful," a violation of any of these provisions is not only a violation of the CLRA, it can also form the basis of an "unlawful" business practices claim under the UCL.

110. The CLRA broadly applies to any transaction involving the sale of goods or services to a consumer. The CLRA is to be liberally construed and applied to promote its underlying purposes, which are to protect consumers and to provide efficient and economical procedures to secure such protection. Cal. Civ. Code § 1760.

JURISDICTION AND VENUE

111. This case is properly maintainable as a class action pursuant to and in accordance with Rule 23(a) of the Federal Rules of Civil Procedure in that:

- The class, which includes hundreds of thousands (if not millions) of persons, is so numerous that joinder of all members is impractical;
- There are substantial questions of law and fact common to the class including those set forth in greater particularity in Paragraph 127 herein;
- This case is properly maintainable as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure, in that the Defendants have

acted or refused to act on grounds generally applicable to all members of the class, thereby making final injunctive or declaratory relief and equitable restitution appropriate.

- Alternatively, this case is also properly maintainable as a class action pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure, in that questions of law and fact common to members of the class predominate over any questions affecting only individual members, and a class action is superior to other available methods for the fair and efficient adjudication of the controversy.

112. This court has jurisdiction over this matter pursuant to 28 U.S.C. §1332(d)(2), in that (1) this is a class action, (2) the injunctive relief sought, restitution, and penalties sought exceeds a value of $5,000,000 and (3) Plaintiff is a citizen of California and Defendants are citizens of Pennsylvania, California, and Delaware.

113. Venue is proper in the Central District of California pursuant to 28 U.S.C. § 1391. Venue is also proper in this district because this action has been centralized in the Eastern District of Pennsylvania by the Panel on Multidistrict Litigation.

THE PARTIES

114. Plaintiff ANDREW RICHARDS is an adult citizen of the State of California, residing in Los Angeles County. He suffers from depressive symptoms and utilized the Impax Product (300mg) to treat his depressive symptoms from January to March 2008. Mr. Richards was prescribed Wellbutrin XL for depression and thereafter took 300mg of Wellbutrin XL, a once-daily formulation, which successfully treated his depression with little or no adverse side effects. Mr. Richards continued to be prescribed "Wellbutrin XL 300-mg" by his physician, and took same up to and through January 2008, when he switched to the Impax Product (300mg). Mr. Richards expended money on the Impax Product (300mg) during this time and at all times believed it was identical to Wellbutrin XL. Mr. Richards continually sought the ease-of-use/compliance of a once-a-day pill. Soon after switching to the Impax Product, his depressive

symptoms returned and/or increased, and on March 12, 2008, he suffered a seizure requiring hospitalization and further visits to his physician. He no longer utilizes the Impax Product.

115. Plaintiff MICKI SACKLER is an adult citizen of the State of California, residing in Los Angeles County. She suffers from depressive symptoms and utilized the Impax Product (150mg) for several months during 2008 to treat her depressive symptoms. Ms. Sackler was diagnosed and was prescribed Wellbutrin XL (150mg) in or around 2006. In or around 2008, Ms. Sackler began to utilize the Impax Product (150mg). She noticed an immediate return of her depressive symptoms, and also began suffering from insomnia. This required Ms. Sackler to return to her physician for treatment. Ms. Sackler expended money on the Impax Product (150mg) and at all times believed it was identical to Wellbutrin XL. Ms. Sackler continually sought the ease-of-use/compliance of a once-a-day pill. She currently takes a generic manufactured by a different company.

116. Defendant IMPAX LABORATORIES, INC. ("Impax") is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California. Impax's officers direct, control, and coordinate's the corporation's activities at this location. Impax manufactures Budeprion XL 300mg and Buproprion Hydrochloride XL (150mg) (collectively, the Impax Product), and has a significant contact or aggregation of contacts to the claims at issue herein. Impax does business in California, its headquarters and principal offices are in California, a significant number of Impax's customers are California residents, and the wrongful acts alleged herein, which have affected members of the proposed class throughout the United States, emanated from Impax's owners, managers, officers, directors, and/or employees in California, and were effectuated in California. Impax's subsidiary, Global Pharmaceuticals, distributes the 150mg Impax Product.

117. Defendant TEVA PHARMACEUTICALS USA, INC. ("Teva") is a Delaware corporation, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania. TEVA is the distributor of Budeprion XL 300mg. It distributes a different 150mg pill manufactured by Anchen which is not implicated in this suit at this time.

CLASS ALLEGATIONS

118. Plaintiffs repeat and re-allege the allegations contained in the preceding paragraphs, as if fully set forth herein.

119. This action is brought by Plaintiffs as a class action pursuant to Federal Rule of Civil Procedure 23(b)(2) on behalf of themselves and a class of other similarly situated persons, applying California's unfair business practices and consumer fraud statutes (California Business and Professions Code section 17200, *et seq.* and the California Consumer Legal Remedies Act, California Civil Code section 1750, *et seq.*). Plaintiffs seek to certify a nationwide class under Federal Rule of Civil Procedure 23(b)(2) applying California law for injunctive relief, restitution and civil penalties. The class Plaintiffs seek to represent is defined as follows:

> **All persons or entities in the United States who purchased, paid-for (in whole or in part), Bupropion Hydrochloride XL (150mg) and/or Budeprion XL (300mg) manufactured by Impax.**
>
> **Excluded from the Classes are Defendants, any parent, subsidiary or affiliate of Defendants, and their officers, directors, and employees, who are or have been employed by Defendants, and any judicial officer who may preside over this action.**

120. In the event a Rule 23(b)(2) or (b)(3) nationwide class applying California law is not suitable, Plaintiffs reserve the right to amend to plead state-by-state subclasses.

121. Plaintiffs expressly disclaim any intent to seek in this suit any recovery for personal injuries that have been suffered by any Class Member. However, Plaintiffs and

Members of the Class are seeking equitable relief in the form of an injunction and restitution (recovery for reimbursement of funds expended to purchase the Impax Product), as expressly provided for by the UCL and the CLRA.

122. The classes satisfy all of the requirements for certification under the Rule 23(b)(2) and 23(b)(3) of the Federal Rules of Civil Procedure. While the requirements under (b)(2) and (b)(3) are different, this case can meet the elements for class certification under both sections.

123. **Numerosity**: The Members of the Class are so numerous that joinder of all Members is impracticable. Although the precise number of Class Members is unknown to Plaintiffs at this time, it can be ascertained through appropriate discovery, and Plaintiffs are informed and believe that hundreds of thousands of persons in the United States paid for Impax Product.

124. **Commonality and Typicality**: This suit poses questions of law or fact which are common to and affect the rights of all Members of the Class. Plaintiffs' claims are typical of the claims of other Members of the Class. Defendants' fraudulent, unfair and unlawful conduct is identical for all members of the class, Specifically, the design, manufacture, marketing, distribution, and/or sale of the Impax Product as referenced above, without disclosure of information regarding the loss of ease of compliance, efficacy and safety related to the defective release technology. Moreover, Defendants' fraudulent, unfair and unlawful omissions and misrepresentations regarding the Impax Product has affected the Members of the Class in similar ways. Members of the Classes have sustained damages as a direct result of the wrongful conduct described herein by purchasing a product that they would not have purchased but for Defendants' wrongful conduct. But for Defendant's omissions and failures to warn, the Impax product would have a far smaller market share.

125. **Adequacy of Representation**: Plaintiffs will fairly and adequately represent and protect the interests of the Members of the Class. Plaintiffs have retained competent counsel who are experienced in complex class actions and intend to diligently and vigorously prosecute the claims alleged herein. Neither Plaintiffs nor their counsel have interests contrary to or conflicting with the interests of the Class.

126. This case also meets the criteria for Class certification under Rule 23(b)(3) because questions of law or fact common to the class predominate over any questions affecting only individual class members, and a class action is superior to other available methods for the fair and efficient adjudication of the controversy.

127. **Predominance of Common Questions of Law and Fact**: Common questions of law and fact predominate for all Class Members over any issues that are particular to any individual Member of the Class. The questions of law and fact common to the Class include, but are not limited to:

- The anticipated defenses present common questions. As identified by Defendants' position statement submitted to the Court on January 26, 2010, Defendants will challenge Plaintiffs' claims based on preemption, primary jurisdiction, and indispensable party. Whether Plaintiffs' claims are preempted and whether the primary jurisdiction doctrine bars Plaintiffs' claims are issues common to the Class;

- Whether Defendants fraudulently, deceptively, and/or unlawfully did not disclose or warn that a patient taking the Impax Product could not take the product without regard to meals and other factors to achieve peak performance;

- Whether Defendants fraudulently, deceptively, and/or unlawfully did not disclose or warn that a patient being switched from Wellbutrin XL (or another Bupropion formulation) to the Impax Product should be carefully monitored;

- Whether Defendants fraudulently, deceptively, and/or unlawfully did not disclose that the time after ingestion to which the Impax Product's maximum level appears in the bloodstream is less than half of what it is

for the name brand product;

- Whether Defendants fraudulently, deceptively, and/or unlawfully did not not disclose that, unlike the name brand product, taking the Impax Product with food (and possibly alcohol) increases the amount of the drug released into the body;

- Whether Defendants fraudulently, deceptively, and/or unlawfully did not disclose that Budeprion XL 300mg was never tested for efficacy and risk of side effects;

- Whether Defendants fraudulently, deceptively, and/or unlawfully did not disclose that Budeprion XL 300mg was never tested for bioequivalence with the Brand Product;

- Whether Defendants fraudulently, deceptively, and/or unlawfully did not disclose the existence of dissolution tests by United States Pharmacopeia ("USP") indicating dissolution of Budeprion XL 300mg varied significantly from the original drug;

- Whether Defendants fraudulently, deceptively, and/or unlawfully did not disclose the numerous complaints of adverse events and loss of efficacy by countless consumers who switched from Wellbutrin XL to the Impax Product;

- Whether Defendants fraudulently, deceptively, and/or unlawfully did not disclose that the dissolving pill technology of the Impax Product begins to metabolize in the upper gastrointestinal tract, rather than in the lower gastrointestinal tract as does Wellbutrin XL;

- Whether Defendants fraudulently, deceptively, and/or unlawfully misrepresented that the Impax Product was an identical product to Wellbutrin XL, different in name only, when the two products actually differ remarkably in terms of their delivery mechanisms and time to peak plasma concentration;

- Whether Defendants fraudulently, deceptively, and/or unlawfully misrepresented that Budeprion XL carried the same level of risk as Wellbutrin XL or non-Impax Product generics;

- Whether Defendants manufactured, distributed, marketed, or sold the Impax Products;

- Whether Defendants engaged in unfair, unlawful and/or fraudulent business practices in violation California Business and Professions Code section 17200, *et seq.*;

- Whether Defendants conduct violates the California Consumer Legal Remedies Act, California Civil Code section 1750, *et seq.*;

- Whether Defendants targeted their business practices at the disabled;

- Whether Defendants' deceptive, unlawful and/or fraudulent business practices and conduct occurred in and/or emanated from California;

- the amount of money Defendants may have acquired by its deceptive, unlawful and/or fraudulent business practices that must be restored to the Class;

- Whether Plaintiffs and the Class are entitled to restitution and the amount of that restitution;

- Whether injunctive relief is proper and the extent of any such relief (e.g., allowable "Dear Doctor" letters, updated entry at the Physician's Desk Reference, notice to pharmacists, pharmaceutical buyers, and state formulary review panels, and/or label updated as allowed without prior FDA approval through the "Changes Being Effected" ("CBE") process); and

- Whether Defendants have violated section 1780(b) of the CLRA and should be ordered to pay a penalty to each member of the Class.

128. **Superiority of Class Action**: A Class action is the best method to fairly and efficiently adjudicate the controversy between the parties in light of the fact that:

(a) Common questions of law and fact predominate over individual questions that may arise, such that there would be enormous economies to the Courts and the parties in litigating the common issues on a class wide instead of a repetitive basis;

(b) A class action is required for optimal deterrence and compensation and for limiting the court-awarded reasonable legal expenses incurred by Class Members;

(c) Should individual Class Members be required to bring separate actions, courts throughout the United States would be confronted with a multiplicity of lawsuits, thus burdening the Court system while also creating the risk of inconsistent rulings and contradictory judgments. In contrast to proceeding on a case-by-case basis, in which inconsistent results would magnify the delay and expense to all parties and the court system, this class action will present far fewer management difficulties while providing unitary adjudication, economies of scale and comprehensive supervision by a single Court.

COUNT 1
(Violations of California's Unfair Competition Law,
Cal. Bus. & Prof. Code § 17200, *et seq.*

129. Plaintiffs repeat and re-allege the allegations contained in the preceding paragraphs, as if fully set forth herein.

130. Defendants engaged in a pattern and practice of omitting material information about the Impax Product in violation of California's Unfair Business Practices Act (Cal. Bus. & Prof. Code § 17200, *et seq.*).

131. California Business and Professions Code section 17200, *et seq.*, provides that unfair competition includes, but is not limited to, "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading marketing."

132. By and through their conduct, including the conduct detailed herein, Defendants engaged in a pattern of unfair business practices by engaging in practices that are immoral, unethical, oppressive, or unscrupulous, the utility of which conduct is far outweighed by the harm done to consumers, physicians, pharmacies, insurance companies, business competitors, and public policy by failing to warn and disclose material information concerning differences with the Brand Product, lack of testing, and adverse reports regarding their product.

133. These omissions, described in greater detail above, include but are not limited to the Impax Product's shortcomings regarding patient compliance, the different release mechanisms, the different release profiles, and the threat of diminished effectiveness and increased adverse events. These were concealed from Plaintiffs and Members of the Class (as well as their physicians, pharmacists, and insurance companies).

134. Defendants also committed acts of unfair competition harming their competitors, including those described above, prohibited by Business and Professions Code section 17200, *et*

seq., by engaging in a pattern of fraudulent business practices within the meaning of Business and Professions Code section 17200, *et seq.*, by failing to warn and disclose material information concerning differences between Wellbutrin XL and the Impax Product, described in greater detail above, including but not limited to the Impax Product's shortcomings regarding patient compliance, the different release mechanisms, the different release profiles, and the threat of diminished effectiveness and increased adverse events. These were concealed from Plaintiffs and Members of the Class (as well as their physicians, pharmacists, and insurance companies).

135. Defendants engaged in these unfair and fraudulent business practices for the primary purpose of collecting money from Plaintiffs and Members of the Class, thereby unjustly enriching Defendants.

136. The actions of Defendants, as alleged herein, also constitute illegal and unlawful practices committed in violation of California's Unfair Competition Act. Defendants knew that making such omissions and misrepresentations was the only way to seize market share. This is evidenced by the Defendants' loss of market share since the filing of this lawsuit – a loss of market share that all independent observers attribute to the limited disclosures made to date – disclosures Defendants were able to hide from the public for years, enriching themselves at the expense of consumers and their competitors.

137. Defendants' conduct is therefore unlawful as defined by the act, as Defendants have violated California Civil Code section 1770(a)(5) and (a)(7), as set forth in detail below, by omitting material information and making factual statements that misled the public about the safety and efficacy of the Impax Product and by omitting facts about the Impax Product that are contrary to statements actually made by Defendants about the Impax Product.

138. As a result of the repeated violations described herein, Defendants received and

continue to receive unearned commercial benefits at the expense of their competitors and the public.

139. Defendants' conduct presents a continuing threat to the public in that doctors continue to prescribe, pharmacists continue to substitute, and consumers continue to purchase the Impax Product without being fully informed of the differences between the Impax Product and Wellbutrin XL and without warnings related to the risk of adverse side effects and lack of efficacy.

140. Such acts and omissions are unlawful and/or unfair and/or fraudulent and constitute a violation of Business and Professions Code section 17200, *et seq.*

141. As a direct and legal result of their conduct as described herein, Defendants have been and will be unjustly enriched by the receipt of ill-gotten gains from customers, including Plaintiffs, who provided money to Defendants based on Defendants' omissions and misrepresentations after Defendants knew of the problems with the Impax Product.

142. Indeed, Plaintiffs expended money on the Impax Product and at all times believed it was identical in all respects to Wellbutrin XL in term of ease-of-use, effectiveness, and risk of side effects. Had Plaintiffs known the truth about the Impax Product, they would not have purchased it or used it.

143. Plaintiffs and other putative class members were misled, and because the omissions and misrepresentations were uniform and material, presumably believed that the Impax Product was as easy-to-use, as effective and no more risky than Wellbutrin XL or other non-Impax Product generics.

144. Plaintiffs and Members of the Class have suffered an actual injury because their money was taken by Defendants as a result of Defendants' omissions and misrepresentations as

described herein.

145. Plaintiffs requests that this Court enter such orders or judgments as may be necessary to restore any person in interest any money which may have been acquired by means of the above-referenced unfair and deceptive practices as provided in California Business and Professions Code section 17203, and for such other relief as set forth below.

COUNT 2
(Violation of the California Consumer Legal Remedies Act, Cal. Civ. Code § 1750, *et seq.*)

146. Plaintiffs repeat and re-allege the allegations contained in the preceding paragraphs, as if fully set forth herein.

147. Plaintiffs bring this claim under the California Consumer Legal Remedies Act, California Civil Code section 1750 *et seq.*, on behalf of themselves and a subclass of the putative class, comprised of those members who purchased the Impax Product within 3 years of the commencement of this action.

148. Pursuant to California Civil Code section 1782, Defendants were notified on June18, 2009 (via letter) of the alleged violations of section 1770 and demanded that the same be corrected. Defendants did not respond.

149. The Impax Product was purchased and used by Plaintiffs and by other consumers similarly situated.

150. Defendants' above-described conduct constituted (and constitutes) the following practices proscribed by Section §1770 of the California Civil Code:

(a) By failing to disclose the differences between the Impax Product and Wellbutrin XL, including omitting that the Impax Product requires more patient self-monitoring to achieve peak performance, was less effective and presented more risks than Wellbutrin XL and other generic alternatives, Defendants were "representing that goods have characteristics, ingredients, uses, benefits, or quantities which they do not have";

(b) By failing to disclose the differences between the Impax Product and Wellbutrin XL, including omitting that the Impax Product requires more patient self-monitoring to achieve peak performance, was less effective and presented more risks than Wellbutrin XL and other generic alternatives, Defendants were "representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another"; and

(c) By failing to disclose the existence of USP tests and/or failing to disclose the lack of testing on the Impax Product, Defendants were "representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another".

151. Defendants' failure to make the disclosures sought in this Complaint had the effect of misleading Plaintiffs, the Class Members and the public for want of communication of the undisclosed facts regarding the differences between the Impax Products and Wellbutrin XL, including that the Impax Product requires more patient self-monitoring, is less effective, presents more risk, and has a different release profile than the Brand Product. These omissions are contrary to what Defendants knew about the Impax Product and contrary to their representations that the Impax Product is identical in all significant respects to Wellbutrin XL.

152. Plaintiffs and Members of the Class are disabled and Defendants' deceitful choice to not disclose or otherwise warn of the differences between the Impax Product and Wellbutrin XL was targeted at disabled persons suffering from major depressive disorder.

153. Plaintiffs suffered injury in fact and lost money as a result of Defendants' omissions and false representations, as Plaintiffs expended money on the Impax Product as a result of the omissions and misrepresentations described in paragraph 71. Plaintiffs did not want the actual Impax Product that was provided. The Impax Product Plaintiffs received was unsatisfactory and worthless..

154. As a direct and proximate result of these unlawful, unfair, and deceptive business practices, Plaintiffs and the CLRA Subclass Class have been damaged and seek restitution of all

monies paid, or some portion of all monies paid, for the Impax Product and injunctive relief as set forth below.

155. Plaintiffs and Members of the CLRA subclass also seek a $5,000.00 penalty per class member for Defendants' unlawful conduct targeted at disabled persons as provided for in California Civil Code section 1780(b).

WHEREFORE, Plaintiffs pray judgment against Defendants, and each of them, as set forth herein below.

NEED FOR INJUNCTIVE RELIEF

156. By committing the acts alleged herein, Defendants, and each of them, have caused and continue to cause irreparable harm for which there is no plain, speedy or adequate remedy at law. In the absence of equitable relief, Members of the Class, Defendants' business competitors, and the general public are in substantial risk of harm.

REQUEST FOR RELIEF

Wherefore, Plaintiffs respectfully request that the Court enter judgment in their favor and against Defendants as follows:

1. An order certifying the Class as defined hereinabove, and any appropriate sub-class thereof, and appointing Plaintiffs and their attorneys to represent the certified class;
2. Ordering that Defendants be required to make restitution to each Plaintiff and Class Member of any and all money or property paid for the purchase of the Impax Product;
3. Other equitable and injunctive relief as allowed by law;
4. Awarding Plaintiffs and the Classes their reasonable attorneys' fees;
5. Awarding Plaintiffs and the Classes pre-judgment and post-judgment interest as provided by law;
6. Awarding Plaintiffs and the CLRA subclass $5,000.00 per class member pursuant to Cal. Civil Code section 1780(b);
7. Awarding Plaintiffs and the Classes their costs of suit herein incurred; and

8. Awarding Plaintiffs and the Classes such other and further relief, including all equitable relief, as may be just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

Respectfully submitted,

GOLOMB & HONIK, P.C.

RH2063

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Dated: February 26, 2009

PLEASE SERVE:

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Wilmington, DE 19808

IN RE:	)	CLASS ACTION
BUDEPRION XL MARKETING AND	)	
SALES PRACTICES LITIGATION	)	2:09-CV-2811 (Lead Case)
(MDL 2107)	)	
	)	
	)	

CASES IN MDL 2107

1. **Central District of California**
   Laura Kelly v. Teva Pharmaceutical Industries Ltd., et al., C.A. No. 2:09-5348

2. **Middle District of Florida**
   Sherri Henchenski, et al. v. Teva Pharmaceutical Industries Ltd., et al., C.A. No. 2:09-470

3. **Eastern District of Louisiana**
   Andrew Morgan v. Teva Pharmaceutical Industries Ltd., et al., C.A. No. 2:09-4409

4. **Eastern District of North Carolina**
   Camilla Snipes Weber v. Teva Pharmaceutical Industries Ltd., et al., C.A. No. 7:09-113

5. **Eastern District of Pennsylvania**
   Steven Rosenfeld v. Teva Pharmaceuticals USA, Inc., et al., C.A. No. 2:09-2811

6. **Northern District of Texas**
   Theresa L. Anderson v. Teva Pharmaceutical Industries Ltd., et al., C.A. No. 3:09-1200

7. **Southern District of Ohio**
   Melissa Latvala, et al. v. Teva Pharmaceuticals USA, Inc., et al., C.A. No. 2:09-795

8. **Northern District of Oklahoma**
   Karen Brown Tims, et al. v. Teva Pharmaceuticals Industries, Ltd., et al., C.A. No. 4:09-649

9. **Western District of Washington**
   Andrea Leighty v. Teva Pharmaceuticals Industries Ltd., et al., C.A. No. 2:09-1640

10. **Southern District of Alabama**
    Amanda Jordan v. Teva Pharmaceuticals, Industries, et al., C.A. No. 1:09-00805

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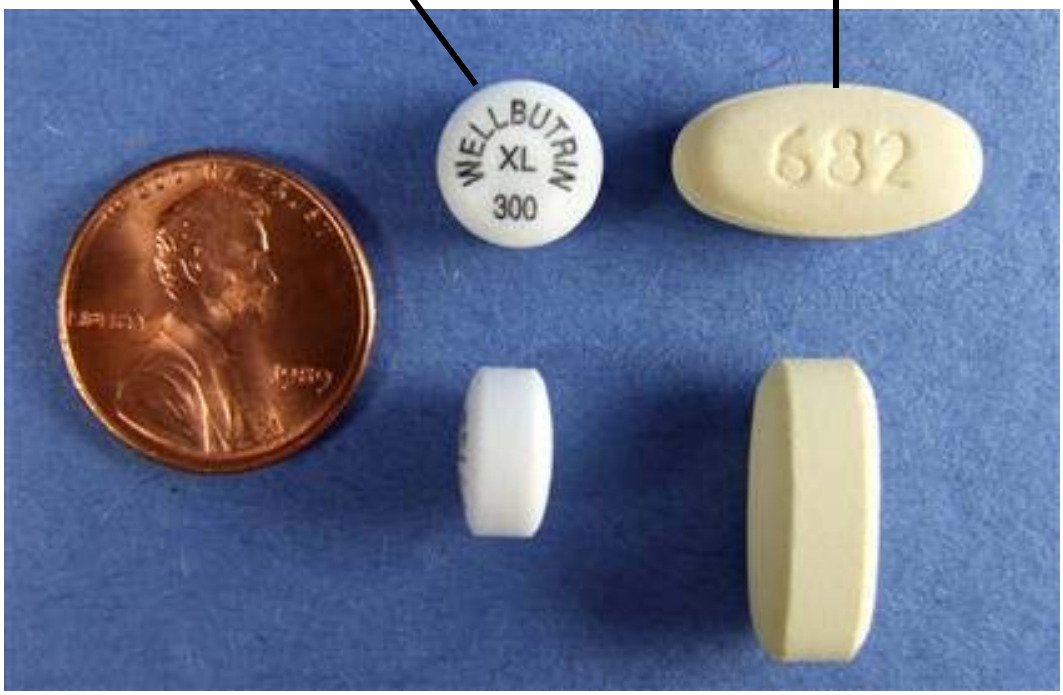
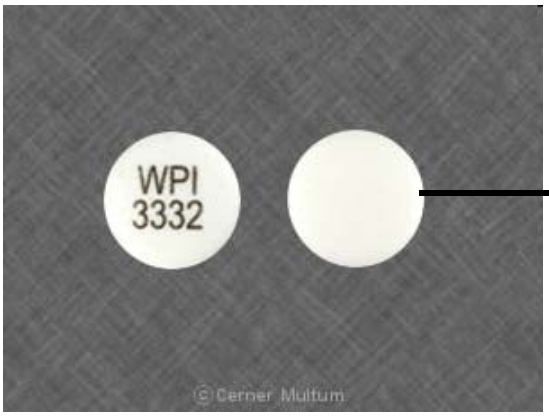
	)	
	)	

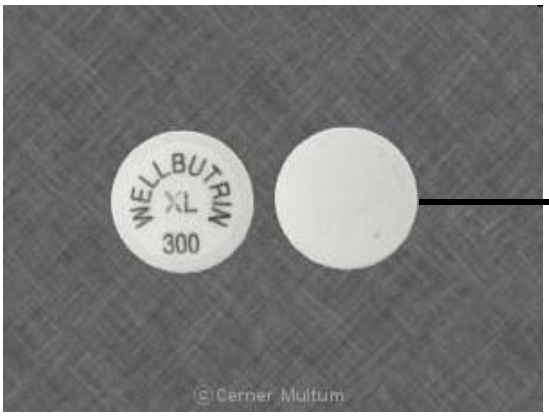
Wellbutrin® XL
300 mg

Impax Product
300 mg





Watson Product
300 mg



Wellbutrin® XL
300 mg